

K091632

**510(k) Summary**



SEP - 3 2009

August 28, 2009

**510(k) SUMMARY OF SAFETY AND EFFECTIVENESS**

**Submitter**

3M ESPE Dental Products  
3M Center, Bldg. 275-2W-08  
St. Paul, MN 55144-1000 USA

**Establishment Registration Number**

2110898

**Contact Person**

Shari Myszka  
Regulatory Affairs Specialist  
Phone: (651) 736-6955  
Fax: (651) 736-1599  
[slmvska@mmm.com](mailto:slmvska@mmm.com)

**Device Name**

SPK Sealant

**Common Name**

Dental Sealant, Pit and Fissure Sealant

**Classification Name**

Pit and Fissure Sealant and Conditioner

**Regulation**

21 CFR 872.3765

**Class**

II

**Panel**

Dental

**Product Code**

EBC

**Predicate Devices**

510(k)	Device Name
K992326	Clinpro Sealant, 3M ESPE-Dental Products
K011491	Heliodeal Clear Chroma, Ivoclar NA, Inc.
K0062344	Grandio Seal, VOCO GmbH
K061997	Enamel L'loc Sealant, Premier Dental Products Company
K073395	Glass Ionomer Protective Coating, 3M ESPE Dental Products

**Description and Technology Equivalence:**

SPK Sealant is moisture activated, light-cured, fluoride releasing pit and fissure sealant that can be applied with or without a phosphoric acid etch step. SPK Sealant is classified as a pit and fissure sealant because the device is composed of a methacrylate-based resin intended for sealing pits and fissures or other tooth surfaces to prevent cavities. Based on the indications for use, technological characteristics, and comparison of the predicate devices, the SPK Sealant has been shown to be safe and effective for its intended use.



## DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Mail Center - WO66-G60  
Silver Spring, MD 20993-0002

Shari L. Myszka, R.Ph., Pharm.D.  
Regulatory Affairs Specialist  
3M Company  
3M ESPE Dental Products  
3M Center, Building 275-2W-08  
St. Paul, Minnesota 55144-1000

SEP - 3 2009

Re: K091632

Trade/Device Name: SPK Sealant  
Regulation Number: 21 CFR 872.3765  
Regulation Name: Pit and Fissure Sealant and Conditioner  
Regulatory Class: II  
Product Code: EBC  
Dated: August 28, 2009  
Received: September 1, 2009

Dear Dr. Myszka:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to <http://www.fda.gov/cdrh/mdr/>.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

 fac

Susan Runner, D.D.S., M.A.  
Acting Division Director  
Division of Anesthesiology, General Hospital,  
Infection Control and Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K091632

Device Name: SPK Sealant

### Indications for Use:

- Sealing pits and fissures, damaged enamel surfaces and exposed dentin surfaces of teeth to prevent caries
- Protective coating for tooth surfaces predisposed to caries or on early non-cavitated lesions (e.g. including use in tooth brush abrasion and root surfaces).
- Covering of caries predilection sites during orthodontic treatment

Prescription Use  AND/OR Over-The-Counter Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

---

Concurrence of CDRH, Office of Device Evaluation (ODE)

*Kai Mulay for MSR*  
(Division Sign-Off)  
Division of Anesthesiology, General Hospital  
Infection Control, Dental Devices

510(k) Number: K091632